

REMARKS

Claims 1-25 are pending. By this Amendment, claims 1, 8, 9, and 12 are amended, new claims 26-29 are added, and no claims are cancelled.

Support for the new claims as well as the amendments to the claims can be found throughout the application as filed; for example, at page 87, lines 10-22 and page 76, line 14 – page 77, line 2. Therefore, no new matter has been added.

**Response to Rejections Under 35 U.S.C. § 103**

Claims 1, 8, and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0114836 (now U.S. Patent No. 7,204,823) to Estes et al. (“Estes”) in view of U.S. Patent Publication No. 2003/0069650 (now U.S. Patent No. 6,944,522) to Karmiy et al. (“Karmiy”). Claims 2-7, 10, and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Estes in view of Karmiy and further in view of U.S. Patent Publication No. 2003/0011646 (now U.S. Patent No. 7,756,722) to Levine et al. (“Levine”). Claims 12-25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Estes in view of U.S. Patent No. 5,814,015 to Gargano et al. (“Gargano”) and further in view of U.S. Patent No. 5,719,761 to Gatti et al. (“Gatti”). These rejections are respectfully traversed, including insofar as they may apply to the amended claims.

Amended claim 1 now recites, in combination with the other elements of the claim, “downloading the operating parameters into the pump by: transmitting the operating parameters over a communication link from the computer to the pump; returning the operating parameters over a communication link from the pump back to the computer; and verifying that the operating

parameters transmitted from the computer to the pump match the operating parameters returned from the pump to the computer.” The method of amended claim 1 is not disclosed, suggested, or evidenced in the references cited in the Office Action, alone or when combined as suggested. In particular, Estes and Karmiy fail to disclose, suggest, or include evidence of “transmitting the operating parameters over a communication link from the computer to the pump; returning the operating parameters over a communication link from the pump back to the computer; and verifying that the operating parameters transmitted from the computer to the pump match the operating parameters returned from the pump to the computer,” as recited in amended claim 1.

Estes merely teaches that “programming can either be entered directly into the infusion device 100 (e.g., on the input device 108), received via the RF programmer 110, or transferred from the communication station 130 (originating, for example, in the computer 132).” (Estes, para. [0035].) Therefore, the non-device based programming disclosure of Estes is limited to simple transfer by a station and receipt by the pump. Similarly, in Karmiy, “When one of the procedures 112 is to be executed by the chemical process machine 118, the procedure editor 106 translates the steps in the procedure into appropriate instructions using the configuration file 114 and transmits the translated instructions to the programmable logic controller 116.” (Karmiy, para. [0027].) Karmiy likewise is limited to a simple transfer by the procedure editor and receipt by the chemical process machine. Both Estes and Karmiy are silent as to returning and verifying operating parameters, as recited in claim 1.

Further, although not cited with respect to claim 1, Levine fails to remedy the deficiencies of Estes and Karmiy because Levine does not disclose, suggest, or include evidence of “transmitting the operating parameters over a communication link from the computer to the

pump; returning the operating parameters over a communication link from the pump back to the computer; and verifying that the operating parameters transmitted from the computer to the pump match the operating parameters returned from the pump to the computer,” as recited in amended claim 1.

Therefore, amended claim 1 is allowable. Claims 2-7 depend from claim 1 and are therefore also now allowable, the rejections of claims 2-7 being traversed but not expressly argued in view of the allowability of the underlying base claim. New claims 26-27, though not treated in the Office Action, depend from claim 1 and are also allowable in view of the allowability of the underlying base claim.

Similar to amended claim 1, amended claim 9 now recites an apparatus with a processor configured to “download the received operating parameters displayed in the cells to the infusion pump by: transmitting the operating parameters over a communication link from the apparatus to the pump; returning the operating parameters over a communication link from the pump back to the apparatus; and verifying that the operating parameters transmitted from the apparatus to the pump match the operating parameters returned from the pump to the apparatus,” in combination with the other elements of the claim. Therefore, at least for the reasons similar to those set forth above with respect to claim 1, claim 9 is also now allowable. Claims 10-11 depend from claim 9 and are therefore also now allowable, the rejections of claims 10-11 being traversed but not expressly argued in view of the allowability of the underlying base claim.

Claim 12 has been amended to correct a minor typographical error. Claim 12 recites a “user-defined identifying name” and “selecting the user-defined identifying name thereby

assigning the set of operating parameters identified by the user-defined identifying name to the delivery program,” in combination with the other elements of the claim.

The Office Action dismisses Applicant’s previous argument in the Amendment filed October 12, 2010, regarding the allowability of claim 12 by quoting language from MPEP § 2145, that “One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references,” and citing *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981) and *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants respectfully submit that the previous arguments did not attack the references only individually, as asserted in the Office Action, and that therefore, *In re Keller* does not apply.

In the case of *In re Keller*, the Examiner’s rejections for obviousness were based upon combinations of a single primary reference and a single secondary reference. “The Examiner rejected claims 1, 2, 6, 7, 9-11, 13, and 14 as obvious in view of Keller taken with Walsh.” *Keller*, 642 F.2d at 421. “The Examiner further rejected claims 1 and 2 as obvious in view of Berkovits taken with Walsh.” *Id.* at 422. To rebut the prima facie case of obviousness established by the Examiner, the applicant in *Keller* filed a single affidavit that “concerns itself mainly with the question of whether the Walsh et al article suggest (sic) the use of digital timing in a cardiac pacer.” *Id.* Thus, the applicant in *Keller* attempted to rebut obviousness based on a combination of references by arguing only about the validity of the secondary reference, Walsh. Therefore, the holding in *Keller*, and its accompanying case *In re Merck*, is limited to the specific situation where the only rebuttal evidence of nonobviousness submitted by the applicant is in the form of an attack on one of the references being combined.

In contrast to the holding in *Keller*, in the previous Amendment in the instant case, Applicant addressed each and every one of the references combined to reject claim 12 for obviousness in the Office Action of May 12, 2010:

None of Estes, Gargano or Gatti, whether taken alone or when combined as suggested in the Office Action, discloses “selecting the user-defined identifying name thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program,” as required by claim 12. The Office Action does not even cite a reference with respect to “thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program.” Gargano, however, does not “assign[] the set of operating parameters identified by the user-defined identifying name to the delivery program.” Refer, for example, to col. 6, lines 15-30, of Gargano, where Gargano discloses only a “safeguard” against the infusion of an incorrect material. Nothing in this cited portion or any other portion of Gargano “assigns” a set of operating parameters to a delivery program. Gatti and Estes are also lacking any disclosure or suggestion of this feature. Further, it would not be obvious, given the emphasis at this portion of Gargano with respect to ensuring the proper drug is used and the statement that the procedure “must be followed,” to use a “user-defined identifying name” with Gargano’s drug name, as the Examiner suggests when citing Gatti.

(Applicant’s Amendment of 10/12/2010.) The instant Office Action appears to miss the crux of Applicant’s previous argument, that none of Estes, Gargano or Gatti, whether taken alone or

when combined as suggested in the Office Action, discloses “selecting the user-defined identifying name thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program,” as required by claim 12. The bounds of the English language and Applicant’s effort to write clearly and concisely generally dictate that each reference be discussed individually as applied to the other obviousness references, rather than trying to combine discussion of all of the references into complex, compound sentences and verbose paragraphs. Applicants therefore emphasize that none of Estes, Gargano or Gatti, whether taken alone or when combined as suggested in the Office Action, discloses or suggests “selecting the user-defined identifying name thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program,” as required by claim 12

Therefore, claim 12 is allowable. Claims 13-18 depend from claim 12 and are therefore also now allowable, the rejections of claims 13-18 being traversed but not expressly argued in view of the allowability of the underlying base claim. New claims 28-29, though not treated in the Office Action, depend from claim 12 and are also allowable in view of the allowability of the underlying base claim.

Similar to claim 12, amended claim 8 now recites, in combination with the other elements of the claim, “each data set in the plurality of data sets containing a user-defined identifying name; storing the plurality of data sets in memory; selecting the user-defined identifying name of one of the plurality of data sets, thereby assigning the set of operating parameters identified by the user-defined identifying name to a delivery program; and running the delivery program.” Therefore, at least for the reasons similar to those set forth above with respect to claim 12, amended claim 8 is also now allowable.

Similar to claim 12 and amended claim 8, claim 19 currently recites “the processor being programmed to assign the set of operating parameters to the delivery program upon selection of the user-defined identifying name and to execute the set of operating parameters,” in combination with the other elements of the claim. At least for the reasons set forth above with respect to claim 12, claim 19 is also now allowable. Claims 20-25 depend from claim 19 and are therefore also now allowable, the rejections of claims 20-25 being traversed but not expressly argued in view of the allowability of the underlying base claim.

### **Conclusion**

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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